K032541

SEP 12 2003

odin
Medical Technologies

Special 510(k) Summary of Safety and Effectiveness

The Following Special 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

Submitter name:	Einav Shlomovitz –Quality and Regulatory Director
Address:	P.O. Box 548, Yokneam Elit 20698, Israel
Phone:	+972-4-959-1010
Fax:	+972-4-959-1011
E-mail:	einav@odin.co.il
Contact Person:	Einav Shlomovitz –Quality and Regulatory Director
Date:	August 4, 2003

807.92(a)(2) - Device Details:

Trade Name and Common Name:	PoleStar N-20 - Magnetic Resonance Diagnostic Device
Classification:	21 CRF 892.1000 Magnetic Resonance Diagnostic Device.
Class:	II MRDD were reclassified by FDA from Class III to Class II effective July 28, 1998.
Product Code:	LNH – Magnetic Resonance Imaging System

807.92(a)(3) – Predicate Devices:

The PoleStar N-20 is comparable to Odin's PoleStar N-10

Medical Device Name	Applicant Name	510(k) Number	Classification
PoleStar N-10	Odin Medical Thechnologies Ltd.	K010850	Class II device

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4) – Device Description:

The PoleStar N-20 utilizes a permanent magnet to acquire 2D single-slice, multi slice, and 3d volume images. A wide variety of pulse sequences are provided to the operator, including spin echo, gradient echo, fast spin echo, and steady state free precession acquisitions. The PoleStar N-20 is a widely open and compact Intraoperative MRI unit intended to be used in a typical pre-existing operating room. The PoleStar N-20 can be moved within the room between procedures, from the operating table to its Magnet Storage Cabinet, thus allowing the operating room to be used for any type of surgery.

807.92(a)(5) – Device Intended Use:

The general purpose of the device as defined in 21 CFR 892.1000:

The PoleStar N-20 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of the extremities and selected sections of the head. The images produced by the PoleStar N-20 reflect the spatial distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

- Anatomical regions: extremities and selected sections of the head.
- Nuclei excited: H-1
- Diagnostic uses: T1, T2, T2* and density weighted imaging.

The PoleStar N-20 is intended to be used intraoperatively in a standard operating room. When interpreted by trained physicians, the MR images provide information that can be useful in determining a diagnosis.

807.92(a)(6) – Substantial Equivalence Comparison Table:

Model / parameter	Odin PoleStar N-10 (K010850)	Odin PoleStar N-20
Clinical application	Extremities and selected sections of the head	Extremities and selected sections of the head
Magnet type	Permanent	Permanent
Field strength	0.12T	0.13T
5 gauss fringe field (radial/axial, m)	1.5	2.2
Shimming	Passive, active	Passive, active
Gradient subsystem Strength mT/m Rise time to 10mT/m msec	 25 <1	 22 <1
Computer system - CPU: - Memory size [MB] array processor - Memory size [MB] storage media	 Pentium 586 64 4xDSP C44 TI 4000 magnetic disk, floppy disk	 Pentium 586 64 4xDSP C44 TI 4000 magnetic disk, floppy disk
number of images stored	5000	5000
Imaging modes: - single - multislice - volume study - other	 Yes Yes Yes No	 Yes Yes Yes No
Reconstruction time: - single slice, sec - multislice, sec - volume sec	 <3/slice <3/slice <20/volume	 <3/slice <3/slice <20/volume

Model / parameter	Odin PoleStar N-10 (K010850)	Odin PoleStar N-20
Cardiac gating (ECG/peripheral)	No	No
Respiratory gating	No	No
Angiography	Optional	Optional
Spectroscopy	No	No
Imaging;		
- pulse sequence	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D
- repetition time, msec	10-5000 increments of 1	10-5000 increments of 1
- echo time, msec	3-150	3-150
- inversion time, msec	N/A	N/A
- slice thickness, mm	2-10	2-10
- scan orientation	Transverse, coronal, sagittal, oblique	Transverse, coronal, sagittal, oblique
- measuring matrix	64x64 to 256x256 steps of 1 in phase encoding	64x64 to 256x256 steps of 1 in phase encoding
- display matrix	1024x768	1024x768
- pixel intensity	0-4095	0-4095
Surface coils:		
- spine	No	No
- knee	Yes	Yes
- neck	No	No
- TMJ	No	No
- extremity	Yes	Yes
- head	Yes	Yes
- breast	No	No
- shoulder	No	No
- others	No	No

Model / parameter	Odin PoleStar N-10 (K010850)	Odin PoleStar N-20
Bore diameter or WxH, cm	24.5x39	25.2x42
Bore features	Open access to patient	Open access to patient
Cooling system type	Closed loop water cooling (Gradients only)	Closed loop water cooling (Gradients only).
Cryogen use	No	No
Magnet weight, kg	330	400
HxWxD, cm	145x96x120	153x97x120
Filed Of View (FOV),cm	5-18	5-20
Dicom 3.0 interface	Yes	Yes
Power requirements: - line voltage, V - Kva - A/C, BTU/hr	 3x208 (3 phase) 16 <10000	 3x208 (3 phase) 15 <10000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

Mr. Einav Shlomovitz
Quality and Regulatory Director
Odin Medical Technologies Ltd.
P.O. Box 548
Yokneam Elit, 20698
ISRAEL

Re: K032541
Trade/Device Name: PoleStar N-20
Regulatory Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: August 4, 2003
Received: August 18, 2003

Dear Mr. Shlomovitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032541

Device Name: **PoleStar N-20**

Indication For Use:

The PoleStar N-20 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of the extremities and selected sections of the head. The images produced by the PoleStar N-20 reflect the spatial distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

Anatomical regions: extremities and selected sections of the head.

Nuclei excited: H-1

Diagnostic uses: T1, T2, T2* and density weighted imaging.

The PoleStar N-20 is intended to be used intraoperatively in a standard operating room. When interpreted by trained physicians, the MR images provide information that can be useful in determining a diagnosis.

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032541